



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/744,444	11/08/96	GOODMAN	M 64-95A

12M1/0922
GREENLEE WINNER AND SULLIVAN
5370 MANHATTAN CIRCLE
SUITE 201
BOULDER CO 80303

EXAMINER

KELLEY, L

ART UNIT	PAPER NUMBER
1211	6

DATE MAILED: 09/22/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 3/4/97 + 5/9/97
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-40 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-40 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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1. This application contains claims directed to the following patentably distinct species of the claimed invention: compounds of claim 1 wherein R_1 may be X, X-CH=CH-, R_3 or R_4 ; wherein R_2 may be H, R_3 or R_4 ; wherein R_3 is X-(CH)_j-C_mH_n-CH_q((CH₂)_x)-; wherein R_4 is Z-(CH₂)_a-CH_b-CH_c-CH_q((CH₂)_x)- where a is 1, 2 or 3; b is 0, 1 or 2; x is 0 or 1; y is 1 or 2; z is 1, 2, 3 or 4; q is 1 or 0; n is 1 or 2; m is 0 or 1; j is 0 or 1; X is any of the halogens listed in claim 1; and Z is any of the Tc-99m chelating structures listed in claim 1.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-13, 15, 17, 19, 20, 21, 24 and 27-40 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Lorraine Greenlee on August 29, 1997 a provisional election was made with traverse to prosecute the species shown on page 57 following Step 98. Affirmation of this election must be made by applicant in responding to this Office

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action. After a thorough examination of the elected species, the examiner has conducted a search of the full scope of the claimed invention. No claims are withdrawn from consideration.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

3. Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country. Applicant has not complied with the requirements of 37 CFR 1.63(c), since:

(1) the oath or declaration does not acknowledge the filing of any foreign application(s). The attachment is not referred to in the body of the oath or declaration. A new oath or declaration is required in the body of which the present application should be identified by application number and filing date.

(2) applicant has not filed a certified copy of the Japanese applications as required by 35 U.S.C. 119(b).

4. Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite with respect to the definition of R_2 because without commas to separate the possible variables, it is not clear from the present language what the distinct possibilities for R_2 are. It is suggested that applicant insert a comma after "if R_1 is R_3 ".

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Claim 1 is further confusing with respect to the R_3 and R_4 definitions because it is not clear whether a cycloalkane ring is formed when R_1 or R_2 is either of R_3 or R_4 . In particular the R_3 and R_4 moieties have two possible places of attachment and it is not clear which point will attach at the R_1 or R_2 position. Furthermore, the portion of claim 1 which reads "such that..." appears to be a proviso requiring that a cycloalkane ring is formed but it is not clear whether this proviso applies to the entire claim or only to the R_4 definition. Also what is meant by such that R_3 is formed? Should there be two bonds attached to R_3 as well as R_4 ? Applicant is advised to amend claim 1 in the definition of the various R groups to recite that R_1 and R_2 *together* may be R_3 or R_4 and to clarify the proviso to specify when the claim requires this compound to be formed. The proviso should also be amended to clarify if R_3 or R_4 is supposed to be attached to the group following the bracket.

The dependent claims each recite either "[a] compound" or "[a] cyclic compound" but the independent claim specifies that the claim is drawn to "[a]n amino acid analog." Thus, there is no antecedent basis for the preambles of the dependent claims. Applicant is advised to amend the claims to recite consistent claim language with the independent claim.

Claim 3 is vague and indefinite because it does not specify the R_1 and R_2 moieties but further defines the subscripts of R_3 . Should claim 3 be dependent on claim 2 instead of claim 1? If not, the claim makes no sense if, for example R_1 is X and R_2 is H or either R_1 or R_2 is R_4 .

Claim 7 is also confusing because it is dependent on claim 6 but does not require that there be an X group.

In claim 40, it is not understood what is meant by "positron emission tomography *of* single photon emission tomography." Should the "of" be "or"? Also in this claim which is dependent on the broad scope of claim 1, it is not understood how the tomographic imaging would be performed when X is F, I, Br or At.

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5. Applicant is advised that should claim 9 be found allowable, claim 11 will be rejected under 35 U.S.C. 101 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

6. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-26 and 40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 08/554,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope with respect to those amino acids of claim 1 where R₁ is X, X-CH=CH- or R₃ and R₂ is H or R₃. The instant claims are

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broader than the claims of the '906 application because the instant claims further allow for R_1 or R_2 to constitute R_4 which contains a Tc-99m chelating structure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claim 1-4, 6-8, 12-13, 15, 17, 19, 21, 24 and 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for radiohalogenated amino acid analogs and tumor imaging using these compounds, does not reasonably provide enablement for the use of non-radioactive halogenated amino acid analogs of applicant's claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

The Federal Circuit has articulated the factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 8 USPQ 1400, 1404 (Fed. Cir. 1988).

The instant claims are directed to radioactive or non-radioactive amino acids, but the instant specification particularly teaches the compounds of the invention to be useful for positron emission tomography (PET) or single photon emission tomography (SPECT). No use is recited for the non-radioactive halogenated amino acids, nor are there any examples where such compounds are synthesized. To a person having ordinary skill in the art, it would constitute undue experimentation to determine how to perform imaging using PET or SPECT technology

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with the non-radioactive amino acid analogs, or to determine a use for such compounds. This experimentation would be required in light of the lack of guidance in the specification as well as the understanding in the art that diagnostic imaging requires a detectably labelled compound to be administered. As evidence of this assertion, applicant's specification is replete with articles directed to diagnostic imaging (PET and SPECT) using detectably labelled molecules.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by either Kollonitsch et al. (U.S. Pat. No. 4,325,961) or Bey et al. (*J. Org. Chem.*, 1979) or Kollonitsch et al. (U.S. Pat. No. 4,325,961).

Kollonitsch et al. disclose a fluorinated amino acid analog at the top of column 5, while Bey et al. teach fluorinated amino acids in Scheme II on page 2734. Note compounds 14a and 16a of Scheme II. These compounds anticipate applicant's claim 1 when R_1 is X where X is F, and R_2 is H where y is 1 and z is 2.

10. Claims 27-39 are allowable *over the prior art* and would be allowed if rewritten in independent form such that the 112 problems discussed above are corrected.

The articles by Heindel et al. and Chiotellis et al. disclose Tc-99m chelates of amino acids but do not teach or suggest the particular structures claimed by applicant.

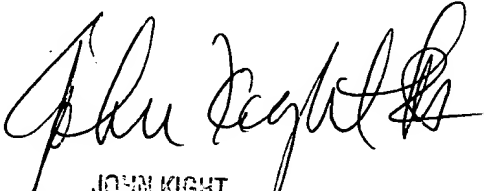
The remaining art on PTO-892 is cited to show the state of the prior art.


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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lara Chapman Kelley whose telephone number is (703) 308-0450. The examiner can normally be reached on Mondays through Thursdays and alternate Fridays from 7:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kight, can be reached on (703) 308-0204. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


JOHN KIGHT
SUPERVISORY PATENT EXAMINER
GROUP 1200


L. Kelley
Sept. 14, 1997